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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/913,159 | 08/10/2001 | Michael Schreiber | 35-213 | 3633 |

7590 08/11/2005

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1100 North Glebe Road
Arlington, VA 22201-4714

EXAMINER

HILL, MYRON G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1648

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,159

Applicant(s)

SCHREIBER, MICHAEL

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 9-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

S.O.D

DETAILED ACTION

This action is in response to the paper filed 12 January 2005.

This action is on claims 4- 8.

Election/Restrictions

Applicant requests reconsideration of the restriction and the assignment of claims 26 and 49-52 in the current group. Claims 26 and 51, as pointed out by Applicant depend from 18 and ultimately 15. The claims are related to Group V as noted by Applicant because they relate to a cloning vector and a method to make a protein mixture which is a method of making the product of Group I and not related to group II. Claims 49 and 50 are methods of preparing vaccines or making proteins and are related to Group VI. Claim 52 is a method of preparing a protein mixture and is related to Group VII. Claims 26 and 49-52 are withdrawn from consideration as requested by Applicant as belonging to different inventive groups.

SEQUENCE RULES

Applicant has added the sequence listing and amended the figure legends to be sequence compliant; however, not all the Descriptions are compliant. Figure 1 is listed correctly because there is a SEQ ID# for each sequence.

Figures 2b and 5 require SEQ ID#s for all the sequences in the figures.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4- 8 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 103

Claims 4- 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fomsgaard (Immunology Letters 1999, Vol. 65, pages 127- 131, from IDS) and Schreiber *et al.* (1997, Journal of Virology Vol. 71, pages 9198- 9205, from IDS) in view of Tartar (2 677 363, from IDS).

The invention is drawn to a DNA vaccine that contains over 10000 different DNA molecules.

Applicant argues that the prior art does not teach a method of making vaccines with over 10^5 or 10^6 variant sequences, that this method makes sequences to as yet

Art Unit: 1648

undiscovered variants, and that this invention provides for promising possibilities for the treatment of HIV not seen in the prior art.

Applicant's arguments have been fully considered and not found persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a method to make, number of variants, sequences to undiscovered variants) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The remark about sequences to undiscovered variants would raise written description issues if in the claims and the remark concerning promising possibilities over the prior art is a remark concerning enablement not how the product is different from the prior art.

The added limitation of "result in different translation products upon expression" does not change the scope of the claim because "randomly distributed sequence combinations" would result different translation sequences because the coding sequence would be changed. Also, knowing the hypervariable loop regions, as illustrated by Tartar and Schreiber et al. would result in a collection of many different sequences. The product (the sum of the different sequences) would appear to be the same as "random" sequences. The "random" sequences might be distinct in a method to make sequences with randomly distributed sequence combinations.

Thus, the rejection is maintained.

Conclusion

No claim is allowed.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

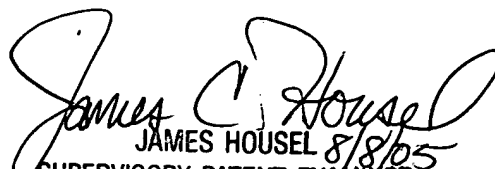
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Myron G. Hill 
Patent Examiner

August 5, 2004


JAMES HOUSEL 8/8/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600